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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,756	12/08/2000	David Mack	A-69439/DJB/JJD	2798

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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/733,756

Applicant(s)

MACK ET AL.

Examiner

Jeanine A Goldberg

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

THE REPLY FILED 13 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 13 August 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☒ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.

Claim(s) objected to: NONE.

Claim(s) rejected: 32-35, 37-39 and 41-51.

Claim(s) withdrawn from consideration: 1-6, 8-30.


8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

J. Goldberg

Continuation of 2. NOTE: Claim 44 has been amended to change the claims. The claims have been amended such that it is unclear how the level of expression of the nucleic acid in different cellular states used to determine the prognosis. .

Continuation of 5. does NOT place the application in condition for allowance because: The after-final response has submitted an exhibit. The exhibit will not be considered because good and sufficient reasons why it was not earlier presented have not been shown. Prior to final rejection, the examiner made several attempts to contact the applicant to obtain a copy of the response discussed in the office action however the applicant did not provide the reference at that time. To submit the exhibit after final, further consideration would be required without an explanation why it was not earlier presented.

The response appears to argue particular thresholds for determining the marker, these values do not appear in the claim (for example the average value of 220), nor do they appear in the specification. It is unclear whether the value of 300 has been extracted from to compare expression of breast tissue expression. Normal breast tissue appears to range from 80-400 with 83% of breast cancer tissues having less than 400 expression. Furthermore, the analysis provided that 2 of 7 normal breast tissue samples had levels higher than 300 is approximately 1/3. Given the claims, in 1/3 of the cases, the increase in expression would not be indicative of breast cancer. Thus, as written the claims appear to lack enablement for the reasons set forth previously.



BJ FORMAN, PH.D.
PRIMARY EXAMINER